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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

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08/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,000	Applicant(s) MIR, KALIM	
	Examiner FRANK W. LU	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 16, 17, 20, 21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 16, 17, 20, 21, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on November 18, 2009 and the amendment filed on September 18, 2009 have been entered. The claims pending in this application are claims 4, 16, 17, 20, 21, 25, and 26. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on September 18, 2009.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on two applications, GB0106635.6, and GB0118879.6, filed in United Kingdom on March 16, 2001 and June 2, 2001 respectively. It is noted, however, that applicant has not filed certified copies of these application as required by 35 U.S.C. 119(b). Although applicant indicated that "[A]pplicant intends to submit these documents prior to grant of any patent based upon this application", since the office has not obtained these certified copies, this objection is maintained.

Claim Objections

3. Claim 4 is objected to because of the following informality: "in the array" in line 1 of step (ii) should be "on the array".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 16, 17, 20, 21, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 4 is rejected as vague and indefinite in view of the phrase “wherein molecules on the array can be individually resolved” because this phrase should not be put in the preamble but should be put in step (i). Furthermore, this phrase does not make sense. Does this phrase mean that “wherein the molecules on the array are in a density such that the molecules can be individually resolved”? Please clarify.

7. Claim 26 is rejected as vague and indefinite because it is unclear why, based on a label which can be detected by optical method, the electrode can transduce an electric signal when a target molecule binds to the labeled immobilized molecule. Please clarify.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 16, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian *et al.*, (WO 00/06770, published on February 10, 2000).

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Regarding claims 4, Balasubramanian *et al.*, teach (i) providing a molecular array comprising a plurality of functional molecules of known identity (ie., polynucleotides with known sequences) immobilized to a solid phase (ie., the solid surface) and (ii) labeling functional immobilized molecules on the array such that remaining labeled individual functional immobilized molecules (ie., the fluorescent labeled polynucleotides) are spatially addressable and capable of being individually resolved by optical methods (ie., optical microscopy) as recited in claim 1 wherein the label can be read by optical methods (ie., optical microscopy) as recited in claim 16, and the label is a single fluorescent molecule (ie., a fluorescent label), nanoparticle or nanorod, or one of a plurality of fluorescent molecules, nanoparticles or nanorods as recited in claim 17 (see pages 2-4, claims 1-21 in pages 20 and 21 and Figure 2).

Regarding claims 20 and 21, Balasubramanian *et al.*, teach that the molecules are selected from defined chemical entities, oligonucleotides, polynucleotides, peptides, polypeptides, conjugated polymers, small organic molecules or analogues, mimetics or conjugates thereof as recited in claim 20 (see page 6). Since Balasubramanian *et al.*, teach that oligonucleotides on the array are chemically synthesized based on cDNA or genomic sequence (see page 14) and hybridize to an organism genomic DNA (see claim 32 in page 22), Balasubramanian *et al.*, disclose that the molecules are cDNAs and/or genomic DNA as recited in claim 21.

Balasubramanian *et al.*, do not disclose labeling only a portion of functional immobilized molecules on the array as recited in claim 4.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 4 by labeling only a portion of functional immobilized molecules on the array in view of the prior art of

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Balasubramanian *et al.*. One having ordinary skill in the art would have been motivated to do so because, by labeling only a portion of functional immobilized molecules on the array, specific functional immobilized molecules on the array would be selected based on the labels of the specific functional immobilized molecules. One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to label specific functional immobilized molecules on the array based on the experimental requirements such that specific functional immobilized molecules on the array would be selected based on the labels of the specific functional immobilized molecules.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian *et al.*, as applied to claims 4, 16, 17, 20, and 21 above, and further in view of Edman *et al.*, (US Patent No. 6,706,473B1, filed on January 24, 2000).

The teachings of Balasubramanian *et al.*, have been summarized previously, *supra*.

Balasubramanian *et al.*, do not disclose that each of the labeled immobilized molecules in step (ii) are immobilized onto a single electrode as recited in claim 25.

Edman *et al.*, teach immobilization of fluorescence labeled DNA oligonucleotides on a streptavidin-agarose and Mn_2O_3 coated amorphous silicon electrode (see column 11, second paragraph and Figures 50A and 50B).

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Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 25 wherein each of the labeled immobilized molecules in step (ii) are immobilized onto a single electrode in view of the prior arts of Balasubramanian *et al.*, and Edman *et al.*. One having ordinary skill in the art would have been motivated to do so because Edman *et al.*, have shown immobilization of fluorescence labeled DNA oligonucleotides on a streptavidin-agarose and Mn_2O_3 coated amorphous silicon electrode (see column 11, second paragraph and Figures 50A and 50B) and the simple substitution of one kind of immobilization method (ie., the immobilization method taught by Balasubramanian *et al.*,) from another kind of immobilization method (ie., the immobilizing polynucleotides on a single electrode taught by Edman *et al.*,) during the process of producing the molecular array recited in claim 4, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the immobilization method taught by Balasubramanian *et al.*, and the immobilization method taught by Edman *et al.*, are used for the same purpose (ie., immobilizing a plurality of functional molecules such as polynucleotides).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

11. No claim is allowed.
12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
August 2, 2010

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